IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Banerjee *et al.*

Serial No.: 09/887,496

Confirmation No.: 7707

Filed: June 22, 2001

For: FORMOTEROL/STEROID BRONCHODILATING COMPOSITIONS AND METHODS OF USE THEREOF

Art Unit: 1617

Examiner: Bahar, M.

I hereby certify that this paper and the attached papers are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202, on this date.

06/17/02
Date

Rita Jennings

TRANSMITTAL LETTER

Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 2327
Arlington, VA 22202

Sir:

Transmitted herewith is a *PETITION UNDER 37 C.F.R. §1.144 - PETITION FROM REQUIREMENT FOR RESTRICTION* for filing in connection with the above-identified application.

☒ The Commissioner is hereby authorized to charge any fee, including any submitted herewith if the attached check(s) is in the wrong amount or otherwise improper or missing, that may be due in connection with this and the attached papers, or with this application during its entire pendency to or to credit any overpayment to Deposit Account No. 50-1213. A duplicate of this sheet is enclosed.

Respectfully submitted,
HELLER EHRMAN WHITE & McAULIFFE LLP

By:
Dale L. Rieger
Registration No. 43,045

Atty Docket No. 18025-1014
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PETITION UNDER 37 C.F.R. §1.144
PETITION FROM REQUIREMENT FOR RESTRICTION

Commissioner for Patents
U.S. Patent and Trademark Office
P.O. Box 2327
Arlington, VA 22202

Dear Sir:

Applicant hereby petitions under 37 C.F.R. §1.144 from a Restriction Requirement in the above-captioned application. Applicant requests removal of the Requirement as between Groups I and III, and as between Groups II and IV.

In view of Applicant's previous election of Group I, Applicant respectfully requests that Groups I and III be combined for examination in this application. Groups I and III are related as a combination/subcombination. Groups II and IV are also related as a combination/subcombination.

STATEMENT OF FACTS

The Requirement was set forth in a written Restriction Requirement, mailed January 7, 2002. The Requirement set forth four (4) Groups for election. Applicant elected, with traverse, Group I, and requested reconsideration of the Requirement as between Groups I and III, and as between Groups II and IV, in the Election and Preliminary Amendment, mailed January

31, 2002. Applicant's arguments were not deemed persuasive. The Requirement was made final in an Office Action, mailed April 24, 2002.

ARGUMENT

Applicant respectfully petitions for reconsideration and removal of the Requirement as between Groups I and III, and as between Groups II and IV, in view of the following remarks.

The Office Action, mailed April 24, 2002, urged that the Restriction Requirement is based on the allegation that the various Groups are patentably distinct because they have different modes of operation. Applicant respectfully submits that restriction of Groups I and III, and restriction of Groups II and IV, is improper for the reasons set forth in detail below.

Restriction of Groups I and III

It is respectfully submitted that the Restriction Requirement as between Group I and Group III is improper because the Groups are related as a combination/subcombination.

As stated in MPEP 806.05(c), paragraphs 1 and 3;

> In order to establish that combination and subcombination inventions are distinct, two-way distinctness must be demonstrated.
> ....
>
> The inventions are distinct if it can be shown that a combination as claimed:
>
> (A) does not require the particulars of the subcombination as claimed for patentability (to show novelty and unobviousness), *and*
> (B) the subcombination can be shown to have utility either by itself or in other and different relations.
>
> *When these factors cannot be shown, such inventions are not distinct.* (Emphasis added.)

It is noted that the two parts of the test for distinctness of a combination and subcombination are to be applied in conjunction. Both (A) and (B) must be satisfied for restriction to be proper. If either one or both of conditions (A) or (B) are not met, then the inventions are not distinct and restriction is not proper.

Group I is directed to pharmaceutical compositions containing formoterol, or a derivative thereof, and a steroidal anti-inflammatory agent, or a derivative thereof. Group III is directed to pharmaceutical compositions containing formoterol, or a derivative thereof; a steroidal anti-inflammatory agent, or a derivative thereof; and one or more of (a) to (j) as follows: (a) a β_2-adrenoreceptor agonist; (b) a dopamine (D_2) receptor agonist; (c) an IL-5 inhibitor; (d) an antisense modulator of IL-5; (e) a tryptase inhibitor; (f) a tachykinin receptor antagonist; (g) milrinone or milrinone lactate; (h) a leukotriene receptor antagonist; (i) a 5-lypoxygenase inhibitor; or (j) an anti-IgE antibody. Hence, Group III is a combination and Group I is a subcombination thereof.

Since two Groups are related as a combination/subcombination, a showing of two-way distinctness is required. In the instant case, if the compositions of Group I are deemed free of the prior art, the compositions of Group III will necessarily be free of the prior art. Thus, a showing of 2-way distinctness cannot be made. Therefore, the compositions of Group III and the compositions of Group I are not restrictable.

Also, if the claims are restricted into these two Groups, applicant ultimately could be granted two patents, one that include claims encompassing pharmaceutical compositions containing formoterol, or a derivative thereof, and a steroidal anti-inflammatory agent, or a derivative thereof; and another with claims directed to pharmaceutical compositions containing formoterol, or a derivative thereof, a steroidal anti-inflammatory agent, or a derivative thereof, and at least one more active agent as recited above, that expire on different dates. If the claims to the combinations (Group III) issued first, a later issuing patent encompassing the subcombination (Group I) could not be held to constitute obvious-type double patenting over the earlier issuing patent. See MPEP 806, which states:

> [w]here restriction is required by the Office double patenting cannot be held, and thus, it is imperative the requirement should never be made where related inventions as claimed are not distinct.

See, also MPEP 804.01, which states:

> 35 U.S.C. 121 authorizes the Commissioner to restrict the claims in a patent application to a single invention when independent and distinct inventions are presented for examination. The third sentence of 35 U.S.C. 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. 121 prohibition applies only where the Office has made a requirement for restriction. The prohibition does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction. This apparent nullification of double patenting as a ground of rejection or invalidity in such cases imposes a heavy burden on the Office to guard against erroneous requirements for restrictions where the claims define essentially the same invention in different language and which, if acquiesced in, might result in the issuance of several patents for the same invention.

It is alleged that Groups I and III are directed to unrelated subject matter since the subject matter of the Groups allegedly have different modes of operation. Applicant respectfully disagrees. The compositions of Groups I and III are intended for the same use (*i.e.*, administration to a patient in need thereof for treatment, prevention, or amelioration of one or more symptoms of a bronchoconstrictive disorder). Therefore, the compositions of both Groups I and III have the same mode of operation. Furthermore, as described in detail above, the compositions of Groups I and III are related as a combination/subcombination for which a showing of two-way distinctness is required. The Office Action fails to provide such a showing.

Since such restriction is improper, reconsideration and withdrawal of the restriction requirement as between Group I and Group III is, therefore, respectfully requested.

Groups II and IV

Applicant traverses the restriction requirement as between Group II, which is directed to methods of treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders by administration of pharmaceutical compositions containing formoterol, or a derivative thereof, and a steroidal anti-inflammatory agent, or a derivative thereof; and Group IV, which is directed to methods of treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders by administration of pharmaceutical compositions containing formoterol, or a derivative thereof; a steroidal anti-inflammatory agent, or a derivative thereof; and administration of one or more of (a) to (j) as follows: (a) a β_2-adrenoreceptor agonist; (b) a dopamine (D_2) receptor agonist; (c) an IL-5 inhibitor; (d) an antisense modulator of IL-5; (e) a tryptase inhibitor; (f) a tachykinin receptor antagonist; (g) milrinone or milrinone lactate; (h) a leukotriene receptor antagonist; (i) a 5-lypoxygenase inhibitor; or (j) an anti-IgE antibody; simultaneously with, prior to or subsequent to the formoterol/steroidal anti-inflammatory agent composition. Group IV (the combination) thus is directed to methods using the compositions used in the methods of Group II (the subcombination) plus administration of at least one more active agent.

Therefore, Group IV is related to Group II as a combination/subcombination for which a showing of two-way distinctness is required (see, MPEP 806.05(c), paragraphs 1 and 3, *supra*). In the instant case, if the methods of Group II are deemed free of the prior art, the methods of Group IV will necessarily be free of the prior art. Thus, a showing of 2-way distinctness cannot be made. Therefore, the methods of Group IV and methods of Group II are not restrictable.

Also, if the claims are restricted into these two Groups, applicant ultimately could be granted two patents, one that includes claims encompassing methods of treatment, prevention, or amelioration of one or more symptoms of

bronchoconstrictive disorders by administration of pharmaceutical compositions containing formoterol, or a derivative thereof, and a steroidal anti-inflammatory agent, or a derivative thereof; and another with claims directed to methods of treatment, prevention, or amelioration of one or more symptoms of bronchoconstrictive disorders by administration of pharmaceutical compositions containing formoterol, or a derivative thereof, and a steroidal anti-inflammatory agent, or a derivative thereof, and administration of at least one more active agent, as described above, that expire on different dates. If the claims to the combinations (Group IV) issued first, a later issuing patent encompassing the subcombination (Group II) could not be held to constitute obvious-type double patenting over the earlier issuing patent. See MPEP 806, paragraph 3, and MPEP 804.01 (*supra*).

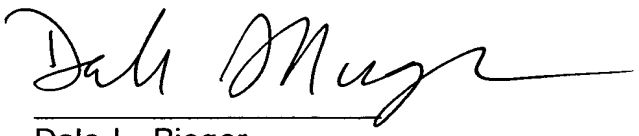
It is alleged that Groups II and IV are directed to unrelated subject matter since the subject matter of the Groups allegedly have different modes of operation. Applicant respectfully disagrees. The methods of Groups II and IV are directed to administration of bronchodilating compositions containing formoterol, or a derivative thereof, and a steroidal anti-inflammatory agent, or a derivative thereof; and administration of bronchodilating compositions containing formoterol, or a derivative thereof, and a steroidal anti-inflammatory agent, or a derivative thereof, and administration of at least one more active agent, as described above, respectively, for treatment, prevention, or amelioration of one or more symptoms of a bronchoconstrictive disorder. Therefore, the methods of both Groups II and IV have the same mode of operation. Furthermore, as described in detail above, the methods of Groups II and IV are related as a combination/subcombination for which a showing of two-way distinctness is required. The Office Action fails to provide such a showing.

Since such restriction is improper, reconsideration and withdrawal of the restriction requirement as between Group II and Group IV is, therefore, respectfully requested.

* * *

In view of the above, Applicant hereby petitions for reconsideration and removal of the Restriction Requirement as between Groups I and III, and as between Groups II and IV. Since Applicant has elected Group I, with traverse, in the instant application, it is respectfully requested that Groups I and III be combined for examination herein.

Respectfully submitted,
HELLER EHRMAN WHITE & McAULIFFE

By: 
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